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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/786,937	BOUCHARD ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 38,39,42,44-46,48-51,56-58,60-63,65,67-70,72-75,78-80,83,84,86-88,90-92,94-100,102-105,107,108,110-116,118,119,122,123 and 126-141.

Continuation of Disposition of Claims: Claims rejected are 38,39,42,44-46,48-51,56-58,60-63,65,67-70,72-75,78-80,83,84,86-88,90-92,94-100,102-105,107,108,110-116,118,119,122,123 and 126-141.

DETAILED ACTION

Response to Amendment

The amendment filed 11 January 2010 is acknowledged. Claims 38, 51, 61, 83, 92, 99 and 115 are currently amended. Claims 47, 59, 89, 97 and 121 are newly cancelled. Claims 38, 39, 42, 44-46, 48-51, 56-58, 60-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-88, 90-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 122, 123, and 126-141 are under examination.

Rejections Withdrawn

All rejections made over claims 47, 59, 89, 97 and 121 are hereby withdrawn in response to Applicants' cancellation of those claims.

Claim Rejections - 35 USC § 112, first paragraph – New Matter

The rejection of claims 61-63, 65, 67-70, 72-75, 78-80, 99-100, 102-105, 107-108 and 110-114 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to Applicants' amendment of the claims to delete reference to the negative limitation "without the administration of a hormone or hormone agonist to induce ovulation," which did not have support in the specification as originally filed.

Claim Rejections - 35 USC § 102

The rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35 U.S.C. 102(b) as being anticipated by Diedrich et al. (cited in previous Office actions, mailed 23 October 2008, 13 September 2006, 15 May 2007 and 20 February 2008) is withdrawn in response to Applicants' amendment of the claims to recite "a single dose of LH and a single dose of FSH" or "a single dose of hMG". Diedrich et al. teach a dosing regimen with gonadotropins lasting approximately 14 days.

Rejections Maintained/New Rejections

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 38, 39, 42, 44-46, 48-51, 56-58, 60-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-88, 90-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 122, 123, and 126-141 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is maintained for reasons of record and the following. Note no arguments or traversals to the rejections were filed with Applicants' remarks.

(A) Some of the issues raised in the previous Office action mailed 22 June 2009 were resolved by Applicants' amendment to the claims. For instance, independent claims 38, 51, 61, 83, 92, 99 and 115 now recite a patient population. Further, claim 38 no longer recites the phrase, "wherein the dose…remains the same during throughout the treatment period", thus resolving the lack of clarity that this phrase introduced in the

claims. Claims 38, 51 and 61 no longer recite the phrase “wherein the LHRH antagonist is administered in a single or dual dosage regimen [of a given amount of milligrams of LHRH antagonist] per dose beginning on menstruation cycle day 1 to 10,” thus resolving the lack of clarity that this phrase introduced in the claims. In addition, claims 46 and 132 no longer recite "a second dose of the LHRH antagonist", thus there is now sufficient antecedent basis in the claims. Further, independent claim 61 no longer recites the phrase “without the administration of a hormone or hormone agonist to induce ovulation,” thus this portion of the claim no longer conflicts the steps requiring administration of hormones. Finally, claim 83 no longer recites administration of the LHRH antagonist for “multiple days”, thus resolving the lack of clarity that that phrase introduced into the claims.

(B) The amended independent claims 38, 51, 61, 83, 92, 99 and 115 now include the clause “wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle,” which introduces new issues.

(i) A proper Markush group may be recited in the conventional manner, or alternatively (see MPEP 2173.05(h)). For example, if “wherein R is a time-point selected from the group consisting of A, B, C and D” is a proper limitation, then “wherein R is A, B, C or D” shall also be considered proper. In the instant case, the lack of clarity arises from the recitation of “day 1 and day 2 of a menstrual cycle.” It is not certain whether "day 1" also means "day 1 of a menstrual cycle" or "day 1 of the luteal phase" or some other time point. Further, “and day in a late luteal phase” is unclear since there is only a

single luteal phase in a menstrual cycle. Further, "and day in" appears to be missing information, for instance, it is not clear which day in the late luteal phase is intended. This aspect of the rejection could be overcome by amending the claims to recite "wherein said method begins on a day selected from the group consisting of day 1 of a menstrual cycle, ~~and~~ day 2 of a menstrual cycle and day X [insert day] in ~~a~~ the late luteal phase of the previous menstrual cycle." Please note that any changes must have support in the specification as originally filed.

(ii) Claims 38, 51, 61 recite "wherein the LHRH antagonist is administered…on menstrual cycle day 1 and continuing through day 10," in step (b) of the claims and similarly, claim 115 recites "beginning on menstruation cycle day 1 to 10" in step (b). Further, claim 83 recites "wherein the LHRH antagonist is administered daily beginning on menstruation cycle day 1 to 10." The introduction of the clause "wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle," renders the claims indefinite with regard to whether the new clause is meant to govern only when the LH, FSH or hMG are administered or whether it governs when ***both*** the LH, FSH or hMG ***and*** the LHRH antagonist are administered. If the phrase "wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle," is meant to govern when the LHRH antagonist is administered, this conflicts with step (b) of claims 38, 51, 61 and 115 because the time table for the dosing regimen in step (b) is different and does not overlap completely with this time table. Further, claims 48, 49,

60, 113, 114, 122, 123 recite administration of additional hormone(s) to induce ovulation, thus it is not clear whether the clause governs the administration of these hormones. Finally, claims 44, 56, 67, 78, 86, 94, 102, 110 and 118 recite that the LHRH antagonists are administered “starting on cycle day 4 to 8.” In summary, the claims still encompass multiple dosing regimens of different hormones occurring during different days of the menstrual cycle, and it is not clear whether the treatment period encompasses administration of all the hormones over the period of a single assisted reproduction cycle, or only until ovulation induction is achieved or even until pregnancy is achieved. The claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant (see MPEP 2171). Given that the claims are to methods of treatment, a defined treatment period must be clearly articulated in the claims.

(C) Claims 39, 70, 105 and 139 recite the limitation "wherein step (a) comprises administering human menopausal gonadotropin (hMG) to induce follicle growth." There is insufficient antecedent basis for this limitation in the claim since the parent claims have been amended to recite “a single dose of LH and a single dose of FSH.” Human menopausal gonadotropin is comprised of a combination of LH and FSH, so the amendment of the parent claims to specify a single dose of LH and a single dose of FSH renders dependent claims 39, 70, 105 and 139 indefinite for lack of antecedent basis.

Finally, the dependent claims 39, 42, 44-46, 48-50, 56-58, 60, 62, 63, 65, 67-70, 72-75, 78-80, 84, 86-88, 90, 91, 94-98, 100, 102-105, 107, 108, 110-114, 118, 119, 122, 123, and 126-141 are also rejected since they depend upon a rejected claim.

Claim Rejections - 35 USC § 112, first paragraph – New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38, 39, 42, 44-46, 48-51, 56-58, 60-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-88, 90-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 122, 123, and 126-141 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amended independent claims 38, 51, 61, 83, 92, 99 and 115 now include the clause "wherein said method begins on a day selected from the group consisting of day 1 and day 2 of a menstrual cycle, and day in a late luteal phase of the previous menstrual cycle," for which there is no support in the specification as originally filed. Applicants state at p. 15 of their Remarks that the treatment period is disclosed at p. 3, lines 26-29, however, no such disclosure is found in the specification as originally filed.

Finally, independent claims 38, 51, 61, 83, 92 and 99 have been amended to recite a single dose of LH and a single dose of FSH or a single dose of hMG, however, there is no support for such a specific limitation. For instance, p. 3, lines 22-25 of the original specification disclose "low dose and short term administration of gonadotropin;" p. 4, lines 13-15 disclose non-gonadotropin stimulated cycles; as noted above, p. 5, lines 14-19 disclose single and dual dosage, but appear to be referring to LHRH antagonist; p. 8, line 12 discloses that a benefit of the protocol is reduction in the need of hMG; Table II discloses longer term dosing of hMG, namely from day 1 (presumably menstrual cycle day 1) until hCG is needed to trigger ovulation. Thus although there is clear support for non-gonadotropin stimulated cycles, nowhere in the specification as originally filed is there support for the specific administration of a single dose of gonadotropin, as currently recited in the claims, namely, "a single dose of LH and a single dose of FSH."

Note that Applicants have amended claim 83 to recite "administered in a dosage regimen of daily doses of 0.25 mg/day until ovulation. Though there is no ipsis verbis support for the recitation "until ovulation", this flows from the specification as originally filed, for instance, the goal of the method is ovulation induction (i.e. obtaining a fertilizable oocyte within a program of COS/ART). Further, the end of p. 3 to the top of p. 4 describe ovulation induction known in the art. Further, the Example at p. 10 describes multiple doses of 0.25 mg/day depending upon follicular development and p. 9 has a flow chart describing when to apply hCG to induce ovulation (i.e. when lead

follicle is 20mm). It flows from this description that the object of the method is to induce ovulation successfully.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35 U.S.C. 102(a) as being anticipated by Olivennes et al. (Human Reprod. 1995; 10: 1382-1386) as set forth in the previous Office action mailed 20 February 2008 is maintained for reasons of record and the following.

Applicants argue at p. 18, 4th paragraph that the Olivennes publication is not available as prior art under 35 U.S.C. 102(b), thus should be withdrawn.

This argument has been fully considered but is not found persuasive. The rejection over the Olivennes publication was made under 35 U.S.C. 102***(a)***.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 38-39, 42, 45-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, 126-141 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent 7,393,834 is maintained for reasons of record.

It is noted that Applicants' have filed a terminal disclaimer 20 November 2009, however, the disclaimer was disapproved because more than 10 practitioners require a power of attorney. Until such time as a proper terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) is filed, the rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 9:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest

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Primary Examiner, Art Unit 1647